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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,614	07/01/2003	Andres Salazar	RIB0201NPA	1456
7590 Max Stul Oppenheimer P.O. Box 50 Stevenson, MD 21153	08/01/2007		EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 08/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/611,614	SALAZAR, ANDRES
	Examiner	Art Unit
	Layla Bland	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3/28/2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 - 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/10/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims benefit of U.S. Provisional Application No. 60/393,713, filed July 3, 2002. Applicant's election without traverse of Group I, claims 1-4, dated March 28, 2005, is acknowledged. Claims 5-10 are withdrawn as being drawn to a non-elected invention. Claims 1-4 are examined on the merits herein.

Claim Objections

Claim 4 is objected to because of the following informalities: the word "claim" should be singular and the claim lacks a period at the end. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omission is as follows: the claim is drawn to an improved method for the manufacture of poly-ICLC. Poly-ICLC is described in the specification as polyriboinosinic-polyribocytidyllic acid stabilized with polylysine and carboxymethylcellulose. However the method of claims 1-4 is drawn only to the addition of polylysine to carboxymethylcellulose and does not include polyriboinosinic-polyribocytidyllic acid. Claim 4 is drawn to a method comprising a polyinosinic acid

Art Unit: 1623

component but it is unclear whether this is due to a mistake in claim 4 or an omission in claim 1.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "at least," "large," "low molecular weight," "greater accuracy," and "increased biological potency" in claim 1 are relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "good vortex" in claim 2 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 4 recites the limitation "the method of claim 1 wherein the polyinosinic acid component solution..." Claim 1 does not include a polyinosinic acid component. There is insufficient antecedent basis for this limitation in the claim. As mentioned above, it is unclear whether the lack of antecedent basis is due to a mistake in claim 4 or an omission in claim 1.

Art Unit: 1623

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy (US 4,349,538, September 14, 1982).

Levy teaches a process for the production of poly-ICLC comprising first pouring a poly-L-lysine solution into a carboxymethylcellulose solution with stirring, and continuing the stirring to redissolve any precipitate which has formed. For best results, the stirring is continued for a period of time sufficient to achieve minimum turbidity, usually about two to three days [column 2, lines 28-41].

Levy is silent on the addition rate of poly-L-lysine to carboxymethylcellulose, other than "slowly."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the stirring and addition rate to achieve "minimum turbidity," as taught by Levy. The skilled artisan would have been motivated to do so with an expectation of success because Levy teaches that minimum turbidity is desirable for the reaction and the skilled artisan would realize that slow addition and vigorous stirring minimizes saturation at the point of addition, which results in decreased precipitation.

Art Unit: 1623

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
July 16, 2007

Shaojia Anna Jiang


Supervisory Patent Examiner
Art Unit 1623
July 16, 2007